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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,294	04/15/1998	MARTIN ROLAND JENSEN	P60953US1	9443

7590

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WASHINGTON, DC 20004

EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/25/2003

260

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/060,294

Applicant(s)

JENSEN ET AL

Examiner

David S Romeo

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 77-132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 77-132 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed March 4, 2002 (Paper No. 24) has been entered. Claims 77-132 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 77-97, 104-106, 110, 117-122, 124, 127-132, drawn to a modified TNF $\alpha$  molecule, classified in class 530, subclass 351.
- II. Claims 98-103, 107-109, 123, drawn to a DNA vaccine comprising a polynucleotide encoding a modified TNF $\alpha$  molecule, classified in class 514, subclass 44.
- III. Claims 111-115, 125, 126, drawn to a diagnostic methods using antibodies to TNF $\alpha$ , classified in class 435, subclass 7.1.
- IV. Claim 116, drawn to a method of making a composition comprising a modified TNF $\alpha$  molecule, classified in class 424, subclass 192.1.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Invention II are related to the polypeptides of Invention I by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis

Art Unit: 1647

and/or conjugation. Further, the polynucleotide may be used for processes other than vaccination, such as a recombinant production of the encoded polypeptide.

The following pairwise combinations of products and methods are independent and distinct, wherein the respective products may neither be produced by, nor required for use in the respective methods: I and III; II and each of III and IV.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case IV could be used for vaccination.

The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps: III and IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

Claims 77-97, 104-106, 110, 117-122, 124, 127-132 are generic to a plurality of disclosed patentably distinct species comprising:

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the C' strand;

Art Unit: 1647

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the C strand;  
a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the H strand;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the E strand;  
a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the F strand;  
a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the B'/C' connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the C'/C connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the C/D connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the D/E connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the E/F connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the F/G connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the G/H connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the H/I connecting loop;

Art Unit: 1647

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the B' strand;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the I strand;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the D strand;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the B' strand and in the B/B' connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the B' strand and in the B'/C' connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the I strand and in the H/I connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the D strand and in the C/D connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the D strand and in the D/E connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the H strand and in the H/I connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the H and I strand and in the entire H/I connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the D and E strand and in the entire D/E connecting loop;

Art Unit: 1647

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the entire C' and C strands and a segment of the D strand;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the E strand and in the E/F connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the E strand and in the D/E connecting loop;

a human TNF $\alpha$  molecule, or a fragment thereof, comprising a substitution in the E strand and in the E/F and D/E connecting loop.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1647

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

  
DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
AUGUST 24, 2003